

U.S. Department of Health and Human Services
United States Public Health Service

National Institutes of Health
Food and Drug Administration
Centers for Disease Control and Prevention

PATENT PRINCIPLES

The primary mission of U.S. Public Health Service (PHS) research laboratories is to acquire new knowledge through the conduct and support of biomedical research to improve the health of the American people. In 1986, Federal laboratories, including PHS research laboratories at the National Institutes of Health (NIH), Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC) were given a statutory mandate to ensure that new technologies developed in those laboratories are transferred to the private sector and commercialized in an expeditious and efficient manner. PHS is cognizant of its role in protecting the public interest as NIH, FDA, and CDC technologies are transferred.

Realization of the considerable anticipated health benefits inherent in PHS-conducted and supported biomedical research will depend in large part on the ability and willingness of private sector technology transfer partners to commercialize new technologies. For potential preventive, diagnostic, and therapeutic products, that willingness almost invariably hinges on the existence of patent protection in the United States and foreign countries for the technology in question.

The United States Patent and Trademark Office (PTO) and courts with jurisdiction over patent matters are the only entities that can make a definitive determination in the United States of the patentability of biomedical research discoveries, including human genetic material. Foreign countries similarly determine the scope and subject matter of patent protection within their boundaries. These determinations require a careful analysis of the particular facts and circumstances of each patent application.

Whether or not to file for patent protection on a given technology is a policy decision made at the discretion of the agency in which a Federal employee inventor works. Accordingly, the PHS has established the following set of principles to guide its agencies in the pursuit and maintenance of U.S. and foreign patent protection for PHS-owned biomedical technology:

- The PHS will seek patent protection on biomedical technologies only when a patent facilitates availability of the technology to the public for preventive, diagnostic, therapeutic, or research use, or other commercial use. Generally a patent is necessary to facilitate and attract

investment by commercial partners for further research and commercial development of the technology, such as where the utility of the patentable subject matter is as a potential preventive, diagnostic, or therapeutic product. However, a patent might also be necessary to encourage a commercial partner to make available for research use important materials or products.

- Patent protection will generally not be sought by the PHS where further research and development is not necessary to realize the technology's primary use and future therapeutic, diagnostic, or preventive uses are not reasonably anticipated. For example, PHS will generally not seek patent protection for commercially valuable research tools (knock-out mice, receptors, cell lines) for the sole purpose of excluding others from using the patentable subject matter without a license. Such materials can be licensed under biological materials licenses or distributed to the research community without further compensation.
- PHS will generally not seek patent protection on a technology unless the commercial or public health value of the technology warrants the expenditure of funds for patenting. If PHS determines that a technology is patentable, but declines to seek patent protection due to low public health or commercial priority, waiver of patent rights to the employee-inventor of the technology may be appropriate and may be considered in accordance with applicable policies and procedures.
- When commercialization and technology transfer can best be accomplished without patent protection, such protection will not be sought. For example, some technologies may be commercialized through non-patent licensing, and some technologies are transferred to the private sector most expeditiously through publication. For those best transferred through publication, patenting and licensing are unnecessary and could inhibit broad dissemination and application of the technology. Methods of performing surgical procedures, for example, could fall within this category.
- With regard to the patenting of research results arising under a Cooperative Research and Development Agreement (CRADA), PHS will evaluate whether to file for patent protection in accordance with these principles, to the extent consistent with the terms of the CRADA and the collaborative relationship.

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- In accordance with a longstanding tradition of scientific freedom, PHS research results are published freely. Publication of research is not to be significantly delayed for the purpose of either filing patent applications on patentable subject matter, or conducting further research to develop patentable subject matter.
- With regard to the patenting of research results which are in early stages of development, PHS will file for patent protection only on research that has a practical utility or a reasonable expectation of future practical utility. Practical utility for this purpose is based on the reasonable expectation of at least one commercial or public health use that is directly and specifically related to the research results in question. For example, the practical utility of a cDNA sequence is determined according to whether a potential use is directly a consequence of the particular sequence, not a use common to all DNA.
- Once initiated, prosecution of patent applications and maintenance of issued patents will continue only as long as there exists a reasonable expectation of transferring the patent rights to a commercial partner through licensing.
- PHS will enforce and defend its patents, where appropriate, either through its own resources, by granting its licensees the right of enforcement and defense as provided by 35 U.S.C. 207 (a)(2), or by referring the matter directly to the Department of Justice. In any case, no litigation may be undertaken in the Federal Court system without approval of the Department of Justice.

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LICENSING PRINCIPLES

The primary mission of U.S. Public Health Service (PHS) research laboratories is to acquire new knowledge through the conduct and support of biomedical research to improve the health of the American people. In 1986, Federal laboratories, including PHS research laboratories at the National Institutes of Health (NIH), Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC) were given a statutory mandate to ensure that new technologies developed in those laboratories are transferred to the private sector and commercialized in an expeditious and efficient manner. PHS is cognizant of its role in protecting the public interest as NIH, FDA, and CDC technologies are transferred.

Realization of the considerable anticipated health benefits inherent in PHS-conducted and supported biomedical research will depend in large part on the ability and willingness of private sector technology transfer partners to commercialize new technologies. For potential preventive, diagnostic, and therapeutic products, that willingness almost invariably hinges on the existence of patent protection in the United States and foreign countries for the technology in question.

PHS generally seeks to patent and license biomedical technologies when a patent will facilitate and attract investment by commercial partners for further research and commercial development of the technology. This is critical where the utility of the patentable subject matter is as a potential preventive, diagnostic, or therapeutic product. However, it could also occur when a patent is necessary to encourage a commercial partner to keep important materials or products available for research use.

Patent protection is generally not sought by PHS where further research and development is not necessary to realize the technology's primary use and future therapeutic, diagnostic, or preventive uses are not reasonably anticipated. For example, PHS will generally not seek patent protection for research tools, such as transgenic mice, receptors, or cell lines. Such materials can be licensed effectively in the absence of patent protection, under royalty-bearing biological materials licenses, or distributed to the research community through non royalty-

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bearing material transfer agreements. For research tools, the public interest is served primarily by ensuring that the tool is widely available to both academic and commercial scientists to advance further scientific discovery. Secondarily, a financial return to the public is obtained through royalties on the rare research tool that has significant commercial value.

In addition, when commercialization and technology transfer can best be accomplished without patent protection, such protection will not be sought. For example, some technologies may be transferred to the private sector most expeditiously through publication. For such technologies, patenting and licensing are unnecessary and could inhibit broad dissemination and application of the technology. Methods of performing surgical procedures, for example, could fall within this category.

In contrast, for technologies with potential preventive, diagnostic, or therapeutic uses, where some type of exclusivity (and therefore patent protection) is necessary for product development, licensing of the patent rights is the primary vehicle for transferring the technology to commercial partners. Due to the importance of effective patent licensing to the development and availability of new products arising from PHS technology, the PHS licensing program is governed by the following principles in marketing, negotiating, executing, and monitoring licenses to PHS patents:

- PHS seeks to ensure development of each technology for the broadest possible applications, optimizing the number of products developed from PHS technology. This is accomplished first and foremost through diligent assertion of inventorship (and thus ownership) rights to PHS technologies in accordance with current patent law. Second, PHS policy is to retain those ownership rights for transfer to the private sector through licensing instead of assignment. This strategy allows PHS to engage in licensing negotiations which ensure the broadest and most expeditious development of new products. Assignment of rights to the commercialization partner would inhibit the ability of PHS to have a meaningful role in monitoring and ensuring the development of the technology.
- PHS seeks to ensure that a licensee obtains the appropriate scope of rights necessary to develop a potential application of the technology. This ensures that as many companies as possible can obtain commercial development rights, resulting in the concurrent development of many potential applications. This is accomplished through:

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- Negotiating non-exclusive or co-exclusive licenses whenever possible. This allows more than one company to develop products using a particular technology, products which may ultimately compete with each other in the marketplace. PHS recognizes that companies typically need an exclusive market position to offset the risk, time, and expense of developing biomedical diagnostic or therapeutic products, however, companies do not necessarily need to achieve that position by exclusively licensing a government technology used to develop that product. Instead, they frequently are able to add their own proprietary technologies to the technology licensed from the government to ultimately achieve some level of uniqueness and exclusivity for the final product.
- Negotiating and awarding exclusive licenses for specific indications or fields of use, based on the license applicant's commercial development ability at the time of application. This prevents one company from tying up license rights to applications that could be concurrently developed by another company.
- Negotiating provisions for mandatory sublicensing by exclusive licensees, particularly where a broad exclusive license is granted, as under a CRADA. CRADA exclusive licenses are granted to patents arising under the CRADA based on the scope of the CRADA research. The research, and therefore the patents, can be broad. Because CRADA partners obtain options to exclusive licenses at the onset of the CRADA, it is usually not appropriate to narrow the field of use to such licenses beyond the original scope of the CRADA research. Thus, PHS requires exclusive licensees to grant sublicenses to broaden the development possibilities when necessary for the public health.
- Negotiating requirements for continuing availability of the technology for further research. Although a technology has been licensed for commercial development, PHS seeks to maintain the availability of that technology for further research uses only by non-profit and for-profit entities. This advances science and stimulates further commercial development.
- PHS seeks to ensure that commercial partners expeditiously develop the licensed technology. This is accomplished through:
 - granting license rights only to fields of use for which the company has submitted an acceptable commercial development plan to bring the technology to practical application. PHS

typically does not grant license rights to venture capitalists, brokers, or other entities that are not in a position to develop the technology directly.

- negotiating specific commercial development milestones and benchmarks with proposed licensees so that development can be assessed and monitored;
- negotiating license execution fees, minimum annual royalty payments, milestone payments, and reimbursement of patent expenses in addition to earned royalty payments. Requiring a company to pay royalties "out of pocket" to acquire and keep the technology ensures that a company is committed to developing the technology and has not licensed the technology merely for competitive advantage.
- PHS seeks to ensure that technologies commercialized under PHS licenses are brought to practical application, offered and maintained for sale, and made reasonably accessible to the public. PHS enhances public access to the benefits of its technology by fostering the development of competing products for the same or similar applications. For example, PHS currently has several CRADAs and licenses which combine the significant expertise of its scientists with the knowledge and resources of different private partners for the development of two types of therapy (gene therapy and recombinant enzyme replacement therapy) for an inherited disease. The only therapy currently on the market to treat this disease is an expensive enzyme replacement regimen derived from placental tissue.
- PHS seeks to obtain a fair financial return on the public's research investment through negotiating royalty-bearing licenses and obtaining payment of patent expenses from licensees.
- PHS seeks to negotiate and obtain public benefits from licensees that are appropriate and consistent with expeditious commercial development and accessibility of the technology.
- PHS monitors the performance of PHS licensees and ensures that its licensed technology is fully developed, through the modification or termination of a license in the event that a licensee is unable to fully develop the rights granted. Modifying an exclusive license to a non-exclusive one, or narrowing the fields of use, allows PHS to license the technology to other companies for further development and sale. This is accomplished through:

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- Negotiating specific grounds for modification or termination of the license. The PHS model exclusive license specifies nine grounds, including failure to meet commercialization benchmarks, failure to keep the licensed technology reasonably accessible to the public, and failure to reasonably meet unmet health care needs.
- Monitoring the commercial development activities of the licensees to determine compliance with the terms of the license agreement.
- Initiating administrative action to modify or terminate license rights where necessary.